

CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

**INITIAL STATEMENT OF REASONS FOR THE
PROPOSED AMENDMENTS OF
SECTION 100080**

HEARING DATE: None scheduled.

DEADLINE FOR SUBMISSION OF COMMENT: January 11, 2010

SUBJECT MATTER OF PROPOSED AMENDMENTS: Acceptable Research Materials

SECTIONS AFFECTED: The proposed amendments apply to Chapter 2 and section 100080 of Title 17 of the California Code of Regulations.

100080 – ACCEPTABLE RESEARCH MATERIALS:

Purpose: The purpose of the proposed amendments to Section 100080 is to augment and to clarify the stem cell lines that may be used in CIRM-funded research.

Subdivision (a): This subdivision describes the criteria for a covered stem cell line to be considered “acceptably derived.” Subparts (1), (2) and (3) insert the word “covered” before “stem cell line” for purposes of grammatical clarity.

Subdivision (a)(2) deletes reference to “human gametes, embryos, somatic cells, or tissue” from the introductory language of that subdivision.

Subdivision (a)(2)(B) deletes reference to “somatic cells or tissue” and adds an exception that states that for embryos originally created using in vitro fertilization for reproductive purposes and are no longer needed for this purpose, “valuable consideration” does not include payments to original gamete donors in excess of “permissible expenses.” The subdivision also now states that original gamete donors may receive reimbursement for permissible expenses, as defined, without reference to determination by an IRB.

Rationale:

Subdivision (a):

The addition of “covered” before “stem cell line” in subparts (1), (2) and (3) are intended to be more grammatically clear and consistent, since the opening sentence of the regulation refers to the requirements for “covered stem cell lines.”

Subdivision (a)(2) deletes reference to the various forms of tissue because they are treated more specifically further down in the subpart.

Subdivision (a)(2)(B) exempts IVF embryos created for reproductive purposes to bring CIRM's regulations into parity with federal policy in identical circumstances. This also ensures that CIRM-funded research is not closed off from access to common sources of materials that CIRM researchers need to use.

Findings and Declarations

Technical, Theoretical or Empirical Studies, Reports or Documents:

A. Documents or Laws:

None.

B. Public Input:

Discussion and public input received at public meetings conducted by the Standards Working Group on September 18 and October 12, 2009, and the ICOC on October 27, 2009.

Copies of the documents referenced above are available at the internet link indicated or at the offices of CIRM located at 210 King Street, San Francisco, California, 94107.

Transcripts and meeting minutes of the meetings referenced in Section "B" are available on CIRM's website, www.cirm.ca.gov under the "Meetings Transcripts" and "Meetings Minutes" links.

Reasonable Alternatives to the Regulation and the Agency's Reasons for Rejecting Those Alternatives:

CIRM determined that no reasonable alternatives considered by the agency, or that have otherwise been identified and brought to the attention of the agency, would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons or businesses than the regulatory action.

Reasonable Alternatives to the Proposed Regulatory Action that Would Lessen Any Adverse Impact on Small Business:

CIRM has not identified any alternatives that would lessen any adverse impact on small businesses.

Evidence Supporting Finding of No Significant Statewide Adverse Economic Impact Directly Affecting Business:

The proposed regulation amendment imposes no restrictions or obligations on businesses. The regulation action expands the materials eligible for use in CIRM-funded research.

*****End*****